

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC. and
BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC. and
BAXTER HEALTHCARE CORPORATION,

Defendants.

Civil Action No. 05-349-GMS

Jury Trial Demanded

BAXTER HEALTHCARE CORPORATION,

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC. and
BAYER HEALTHCARE LLC,

Counterdefendants.

PUBLIC VERSION

**BAXTER'S MEMORANDUM IN OPPOSITION TO
PLAINTIFFS' MOTION *IN LIMINE* NO. 5 TO PRECLUDE
CERTAIN EXPERT TESTIMONY OF THOMAS J. KINDT, Ph.D.**

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I. INTRODUCTION

Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC (“Plaintiffs”) seek to reap the benefit of telling the Patent Office that the prior art solvent/detergent (“S/D”) treatment “always” increases ACA and, at the same time, not be bound by those same representations before this Court. Plaintiffs cannot have it both ways – either S/D treatment does not always (or inherently) increase ACA, and the ‘191 patent should be found unenforceable for inequitable conduct, or Dr. Kindt should be permitted to testify at trial that Plaintiffs’ admissions that S/D treatment “always” increases ACA compel invalidity of the ‘191 patent.

Plaintiffs rely on isolated and conclusory testimony at the end of two days of deposition to argue that Dr. Kindt improperly employed hindsight. At no time, however, did Dr. Kindt state that he used hindsight in his obviousness analysis, and his explanation of his analysis demonstrates it was proper. The jury is entitled to hear Dr. Kindt’s opinions and decide the propriety of his analysis.

Finally, Dr. Kindt should be permitted to rely on all obviousness combinations listed in his expert report. Plaintiffs were aware of these combinations and had an opportunity to depose Dr. Kindt on them, so would suffer no prejudice if he discusses them at trial.

II. FAIRNESS REQUIRES THAT DR. KINDT BE PERMITTED TO OPINE REGARDING INHERENCY

The named inventor of the ‘191 patent expressly represented to the Patent Office that the prior art S/D processes “always” increase ACA.

We have found that **using the SD process [defined in the ‘191 patent as the prior art Neurath process]** to treat ISG preparations ... results in a product ... with **unacceptably high levels of ACA**. Elevated ACA levels were **always** detected at the sterile bulk stage ... of all [TNBP]/detergent treated IGIV preparations (Rogaski Opp. Decl., Ex. 13, Col. 2:6-14, emphases added.)

Thus, **using the prior art SD process** ... yields a product which has **high ACA** and is unsuitable for intravenous administration. (*Id.* at Col. 7:20-24,

emphasis added)

... following the prior art results in a product with an unacceptable level of ACA. (*Id.* at Col. 10:25-26, emphasis added)

If, as Plaintiffs suggest in their motion, these representations upon which the '191 patent issued are false, the '191 patent was obtained through inequitable conduct.¹ Because the '191 patent issued in part based on these representations that the prior art S/D treatments "always" increase ACA, this finding must be applied equally to the prior art.

Plaintiffs complain that Dr. Kindt cannot assert inherency when he does not believe from a technical standpoint that S/D treatment would "always" increase ACA. In so doing, Plaintiffs attempt to shift the focus away from their own admissions during prosecution. Legally, the inventor represented to the Patent Office that prior art S/D treatments "always" (or inherently) increase ACA. Dr. Kindt must be entitled to rely on the inventor's representations in his invalidity opinion.

III. DR. KINDT CONDUCTED A PROPER OBVIOUSNESS ANALYSIS

The Supreme Court recently confirmed that obviousness requires "an expansive and flexible approach." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ____ (2007), 2007 U.S. LEXIS 4745, *32 (Rogaski Opp. Decl., Ex. 14). "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. ... Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." *Id.* at *42. Here, Plaintiffs improperly urge this Court to apply "rigid preventative rules" to prevent Dr. Kindt from explaining to the jury his

¹ In fact, Baxter International Inc. and Baxter Healthcare Corporation ("Baxter") filed a motion to amend their counterclaim to assert a count of inequitable conduct based on these misrepresentations. D.I. 165. This motion is still pending.

analysis of how and why a skilled artisan in 1995 would have understood and combined references. Plaintiffs' procedural gamesmanship should not be countenanced.

On multiple occasions throughout his two-day deposition, Plaintiffs' counsel asked Dr. Kindt about his obviousness analysis. Using his own words, he aptly and consistently described his analysis as:

REDACTED

Dr. Kindt's testimony makes abundantly clear that he considered the knowledge of a skilled artisan "at the time" of the invention and how a skilled artisan would approach a problem and follow the literature to a solution. Specifically, he considered what the various prior art references taught about a process of making intravenous immunoglobulin ("IGIV") solutions. He also explained that he considered references that referred to each other or otherwise addressed the problem of developing an IGIV solution that could be intravenously administered. None of this even suggests the use of hindsight or any improper analysis.

At the end of the second day of his deposition, clearly unsatisfied with Dr. Kindt's prior answers showing his proper analysis, Plaintiffs' counsel returned to the question of Dr. Kindt's obviousness analysis. (Rogaski Opp. Decl., Ex. 16, pp. 242-244.) It is that testimony, not the

testimony identified above, upon which Plaintiffs now rely.

Even the testimony upon which Plaintiffs rely does not show any improper analysis. An obviousness analysis requires, *inter alia*, evaluating the state of the art and comparing the prior art to the claims to ascertain similarities and differences (the “*Graham*” factors). *KSR*, 2007 LEXIS 4745 at *17-18. Plaintiffs’ arguments would eviscerate the *Graham* factors. They complain that Dr. Kindt “started with the ‘191 patent in Claim 1 that described the process.” Motion at 4. Yet, to undertake a *Graham* analysis, an expert **must** start with the claim, as did Dr. Kindt. Plaintiffs then complain that “Dr. Kindt tr[ie]d to find pieces in this body of prior art that you could put together that would satisfy all elements of the claim.” *Id.* In fact, these were Plaintiffs’ counsel’s words. In Dr. Kindt’s words, his analysis considered REDACTED

(Rogaski Opp. Decl., Ex. 15, 122:17-123:6.) Rather than reflect hindsight, Dr. Kindt’s testimony reveals that he properly followed the *Graham* analysis, by considering the state of the art with respect to the technology discussed in the ‘191 patent and determining the similarities (many) and any differences (few) between the prior art and the ‘191 patent. Plaintiffs’ complaints are misguided.

IV. DR. KINDT SHOULD BE PERMITTED TO RELY ON OBVIOUSNESS COMBINATIONS IDENTIFIED IN HIS REPORT

Plaintiffs were on notice of the various combinations Dr. Kindt intends to rely upon at trial because they were listed in his expert report. (Rogaski Opp. Decl., Ex. 10.) Rather than explore those combinations at his deposition, Plaintiffs’ counsel chose instead to require Dr. Kindt to write out the combinations from his report onto pieces of paper. While his lists are mostly complete, he missed a few combinations that are in his expert report. Plaintiffs seek to exclude those few combinations at trial. Such a procedural tactic should be soundly rejected as

Plaintiffs will suffer no harm from Dr. Kindt's testimony about those combinations at trial.

Plaintiffs chose not explore Dr. Kindt's obviousness combinations during his deposition – even those on his lists – so cannot claim they were deprived of the opportunity to depose Dr. Kindt on these few additional combinations. And, in fact, Plaintiffs make no attempt to show any prejudice. They simply assert that Plaintiffs' misguided deposition strategy should somehow limit Dr. Kindt's opinions at trial. This is not a proper basis for exclusion of Dr. Kindt's obviousness opinions. Consequently, Dr. Kindt should be permitted to testify about these combinations at trial.

V. CONCLUSION

For the reasons set forth above, Baxter requests that this motion *in limine* be denied.

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CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on May 14, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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